IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC, FOREST LABORATORIES HOLDINGS, LTD., ALLERGAN USA, INC., and IRONWOOD PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd., Allergan USA, Inc., and Ironwood Pharmaceuticals, Inc. (collectively, "Plaintiffs"), for their Complaint against Teva Pharmaceuticals USA, Inc., hereby allege as follows.

PARTIES

1. Plaintiff Forest Laboratories, LLC (successor-in-interest to Forest Laboratories, Inc.) is a Delaware limited liability company having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

2. Plaintiff Forest Laboratories Holdings, Ltd. is an Irish corporation having a principal place of business at Canon's Court, 22 Victoria Street, Hamilton HM12, Bermuda.

3. Plaintiff Allergan USA, Inc. is a Delaware corporation having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054 (referred to herein, together with Forest Laboratories, LLC and Forest Laboratories Holdings, Ltd., as "Forest").

4. Plaintiff Ironwood Pharmaceuticals, Inc. ("Ironwood") is a Delaware corporation having a principal place of business at 301 Binney Street, Cambridge, Massachusetts 02142.

5. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva") is a Delaware corporation having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Upon information and belief, Defendant Teva manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

6. This is a civil action for the infringement by Teva of United States Patent No. 9,708,371 ("the '371 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and arises from Teva's filing of an Abbreviated New Drug Application ("ANDA") with the FDA seeking to commercialize generic versions of Plaintiffs' Linzess® brand linaclotide capsules throughout the United States, including this judicial district, before the expiration of the '371 patent.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Teva by virtue of the fact that, *inter alia*, Teva has committed, or aided, abetted, induced, contributed to, and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs in Delaware. Teva has participated in the preparation and/or filing of ANDA No. 209568 ("the Teva ANDA") seeking FDA approval to market and sell generic versions of Plaintiffs' branded prescription drug product Linzess® ("the Teva Generic Products") – and has

plans to manufacture, distribute, market, and/or sell the Teva Generic Products throughout the United States, including in this judicial district – before the '371 patent expires. This Court has personal jurisdiction over Teva for the additional reasons set forth below and for other reasons that will be presented to the Court if such personal jurisdiction is challenged.

9. This Court has personal jurisdiction over Teva by virtue of, *inter alia*, the fact that Teva is a Delaware corporation.

10. Venue is proper in this judicial district as to Teva pursuant to 28 U.S.C. § 1400(b).

THE PATENTS

11. On July 18, 2017, the '371 patent, titled "Treatments for Gastrointestinal Disorders," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO"). Ironwood is the sole owner of the '371 patent. Forest is the exclusive licensee of the '371 patent with respect to commercializing pharmaceutical products containing linaclotide in the United States. A copy of the '371 patent is attached hereto as Exhibit A.

12. Forest Laboratories, LLC holds New Drug Application ("NDA") 202-811 for Linzess® brand linaclotide capsules. Linzess® is approved for the treatment of irritable bowel syndrome with constipation ("IBS-C") and chronic idiopathic constipation ("CIC"). United States Patent Nos. 7,304,036 ("the '036 patent"), 7,371,727 ("the '727 patent"), 7,704,947 ("the '947 patent"), 7,745,409 ("the '409 patent"), 8,080,526 ("the '526 patent"), 8,110,553 ("the '553 patent"), 8,748,573 ("the '573 patent"), 8,802,628 ("the '628 patent"), 8,933,030 ("the '030 patent"), and the '371 patent are all listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Linzess®.

13. Allergan USA, Inc. is the exclusive distributor of Linzess® in the United States.

ACTS GIVING RISE TO THIS ACTION

14. Upon information and belief, on or before October 21, 2016, Teva submitted the Teva ANDA to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Teva ANDA seeks FDA approval for the commercial manufacture, use, and sale of generic capsule products containing 145 μg and 290 μg of linaclotide as the active ingredient.

15. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, the Teva ANDA previously included allegations that the claims of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, the '553 patent, the '573 patent, the '628 patent, and the '030 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Teva Generic Products. Plaintiffs received written notification of the Teva ANDA and its previous § 505(j)(2)(A)(vii)(IV) allegations with respect to '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, the '553 patent, the '573 patent, the '628 patent, and the '030 patent no earlier than October 24, 2016, and timely brought suit against Teva for infringement of those patents on or about November 30, 2016 in *Forest Laboratories, LLC, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 16-1114-RGA (D. Del.).

16. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Teva recently amended the Teva ANDA to include, for the first time, allegations that the claims of the '371 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Teva Generic Products. None of the Plaintiffs received written notification of Teva's amendment of the Teva ANDA to add § 505(j)(2)(A)(vii)(IV) allegations with respect to the '371 patent any earlier than September 11, 2017.

17. Teva's amendment of the Teva ANDA to add § 505(j)(2)(A)(vii)(IV) allegations with respect to the '371 patent constitutes infringement of one or more of Claims 1-28 of the '371 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Teva commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, any of the Teva Generic Products, or induces or contributes to any such conduct, it would further infringe these claims of the '371 patent under 35 U.S.C. § 271(a), (b), and/or (c).

18. Teva has infringed one or more of Claims 1-28 of the '371 patent under 35 U.S.C. § 271(e)(2)(A), and will further infringe one or more of these claims under 35 U.S.C. § 271(a), (b), and/or (c) if the Teva Generic Products are commercially made, used, offered for sale, or sold in the United States, or imported into the United States, because, *inter alia*, the Teva Generic Products and the methods of using the Teva Generic Products – *e.g.*, by doctors, pharmacists, healthcare providers, and patients according to Teva's proposed package insert – will meet each and every claim element of one or more of Claims 1-28 of the '371 patent either literally or under the doctrine of equivalents.

19. Upon information and belief, Teva has participated in, contributed to, aided, abetted, and/or induced infringement of the '371 patent and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '371 patent once the Teva Generic Products are commercially made, used, offered for sale, or sold in the United States, or imported into the United States.

20. Upon information and belief, Teva has knowledge that if it were to receive approval from the FDA to market the Teva Generic Products described in the Teva ANDA and make the Teva Generic Products available for sale and/or use by others – *e.g.*, by doctors, pharmacists, healthcare providers, and patients – during the proposed shelf life of the Teva

Generic Products before expiration of the '371 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. Upon information and belief, Teva has knowledge of such infringing use and also knows that the products described in the Teva ANDA are not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather are especially made and/or adapted for use in the direct infringement of the '371 patent.

21. Upon information and belief, Teva was aware of the '371 patent prior to amending the Teva ANDA to add § 505(j)(2)(A)(vii)(IV) allegations with respect to that patent. Upon information and belief, the proposed label for the Teva Generic Products will induce others – *e.g.*, doctors, pharmacists, healthcare providers, and patients – to infringe the '371 patent and Teva possesses the specific intent to induce and encourage others to infringe those patents.

22. Teva's actions render this an exceptional case under 35 U.S.C. § 285.

23. Plaintiffs will be irreparably harmed by Teva's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Teva has infringed the '371 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Teva's ANDA identified in this Complaint shall not be earlier than the expiration date of the '371 patent, including any extensions or exclusivities;

C. That Teva, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or

importing into the United States, the Teva Generic Products, and any other product that infringes or induces or contributes to the infringement of the '371 patent, prior to the expiration date of the '371 patent, including any extensions or exclusivities;

D. That Plaintiffs be awarded monetary relief if Teva commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, the Teva Generic Products, or any other product that infringes or induces or contributes to the infringement of the '371 patent prior to the expiration of the '371 patent, including any extensions or exclusivities, and that such monetary relief be awarded to Plaintiffs with prejudgment interest;

E. That Plaintiffs be awarded the attorneys' fees, costs, and expenses that they incur prosecuting this action under 35 U.S.C. § 285;

F. That Plaintiffs be awarded all of the relief they seek in their related litigation against Teva, *Forest Laboratories, LLC, et al. v. Teva Pharmaceuticals USA, Inc., et al*., Civil Action No. 16-1114-RGA (D. Del.); and

G. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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